K102806

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510(k) SUMMARY

JAN 5 2011

510(k) Owner:	Allergan Medical Contact: Micah Schloss Phone: 805-961-5828 Fax: 714-796-9724	
Date Summary Prepared:	September 27, 2010	
Device:	Trade Name:	NATRELLE® 133 Tissue Expander with Suture Tabs
	Common/Classification Name:	Expander, Skin, Inflatable
	Classification Regulation:	LCJ (Unclassified)
Predicate Devices:	NATRELLE® Style 133 Series Tissue Expander Matrix (K862203)	

Device Description:

Allergan's Tissue Expanders are constructed from silicone elastomer and consist of an expansion envelope with a BIOCELL® textured surface, three suture tabs, a MAGNA-SITE® integrated injection site (incorporating a titanium needle guard), and a stable, reinforced base to enable outward expansion. The three suture tabs are attached to the posterior surface of the shell at approximately the 12 o'clock, 4 o'clock, and 8 o'clock positions of the tissue expander. The Tissue Expanders are available in seven styles and each style consists of six sizes for a total of 42 products, to meet diverse surgical needs.

The MAGNA-SITE® injection site and MAGNA-FINDER® Xact external locating device contain rare-earth, permanent magnets for an accurate injection system. When the MAGNA-FINDER® Xact external locating device is passed over the surface of the tissue being expanded, its rare-earth, permanent magnet indicates the location of the MAGNA-SITE® injection site. All injection sites contain a self-sealing port and a titanium needle guard to prevent inadvertent puncture through the base of the injection site.

Intended Use:

The NATRELLE® Tissue Expanders are used in breast reconstruction following mastectomy, treatment of underdeveloped breasts, and treatment of soft tissue deformities. The expanders are intended for temporary subcutaneous implantation and are not intended for use beyond six months.

Technological Characteristics:	The predicate device and the modified device utilize the same fundamental technology: • A silicone expansion envelope with a BIOCELL® textured surface, which expands with sequential injections of sterile saline • A silicone injection site, with self-sealing port, a magnetic locating system and a titanium needle guard
Biocompatibility Data:	In accordance with ISO 10993-1:2009 and Allergan's internal standards and procedures, a biocompatibility review of Mohawk P118 polyester mesh was performed. Based on the test results, the material is approved and considered qualified for use in the suture tabs of NATRELLE® Tissue Expanders. All other materials used in NATRELLE® Tissue Expanders are identical to those used in the predicate device.
Performance Testing:	Suture tab bond integrity was tested in accordance with ISO 14607:2007(E), ASTM F1441 and Allergan's internal standards and procedure, and predetermined acceptance criteria were met.
Conclusions:	The device passed all preclinical testing, indicating that no new questions of safety and effectiveness are introduced with the proposed modification. NATRELLE® 133 Tissue Expander with Suture Tabs is substantially equivalent to Allergan's currently marketed NATRELLE® Style 133 Series Tissue Expander Matrix (K862203).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Allergan Medical
% Mr. Micah Schloss
Associate Regulatory Analyst
71 S. Los Carneros Road
Goleta, California 93117-5506

Re: K102806
Trade/Device Name: NATRELLE® Tissue Expanders
Regulation Number: 21 CFR 878.3600
Regulation Name: Tissue expander
Regulatory Class: II
Product Code: LCJ
Dated: December 3, 2010
Received: December 8, 2010

Dear Mr. Schloss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102806

Device Name: NATRELLE® Tissue Expanders

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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